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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,529	03/01/2000	NICHOLAS P. HARBERD	620-91	2031

7590 02/06/2002

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 02/06/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/485,529

Applicant(s)

HARBERD ET AL.

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 and 48-56 is/are pending in the application.
- 4a) Of the above claim(s) 10-13, 17-25 and 48-54 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 4, 5, 26 and 27 is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-9, 14-16, 28-46, 55 and 56 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Receipt is acknowledged of Applicant's response to the requirement for restriction filed 10/03/01. In response to Applicant's request for clarification about the grouping, the restriction requirement is set between the inventions of Groups I-V. Group I is intended to encompass claims 1-49. Claims 14-27 were inadvertently omitted in the last Office action. Applicants have elected Group 1 and SEQ ID NO:104. However, upon further consideration it has been determined that claims (in Group I) drawn to SEQ ID NO:104 and SEQ ID NO:7 (and their encoding polynucleotides SEQ ID NO:105 and 14, respectively) encompassing claim 1-9, 14-16, 26-46, and 55-56, can be examined together without bearing any undue search burden on the Examiner. Applicant's election with traverse is acknowledged. The traversal is on the ground(s) that the unity of the invention is not affected by the cited prior art references (Herbart et al and Chiang et al) as none of the prior art references discloses an isolated Rht polynucleotides/polypeptide as disclosed by the Applicant. Applicants also assert that all the claims including all the sequences in this application relate to a single inventive concept which is Rht polypeptides and nucleic acids encoded them, and therefore all the Groups, I-V, with all the claimed sequences should be examined together. These arguments have been fully considered but not all are persuasive.

Applicants' argument regarding the cited references against the unity of the invention is persuasive as none of the prior art references teaches or suggests the disclosed Rht polynucleotides/polypeptide sequences. However, the argument that Groups I-V and all the claimed sequences possess a special technical feature which corresponds to Rht polypeptides and

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polynucleotides encoding them and should be examined together, is not persuasive. First of all, the inventions of Groups I-V are distinct inventions for the reasons disclosed in the last Office action. Two inventions are considered to be independent if they are not shown to be obvious over each. In this case, claims drawn to rht polynucleotide sequences are unobvious over the claims drawn to their encoded polypeptides or antibody for the polypeptide, absent evidence to the contrary. Though Applicant appears to assert that a protein sequence encoded by a particular DNA sequence, the claims themselves are not limited to particular DNA/protein sequences only. For example, Applicant uses sequence similarity language and residues or fragment limitations to expand the scope of any DNA/protein sequence claimed. Moreover, Applicant has not stated that the particular polynucleotide sequences are unpatentable over corresponding protein sequences or the antibody for that protein. In addition, both the literature and sequence search of Groups I-V are divergent , and searching them together will pose series search burden on the Examiner, even if some of the search overlap. Therefore, Groups I-V are independent and distinct inventions and can not be examined together.

In response to Applicants's arguments regarding the examination on the merits for claims that encompass the "entirety of the subject invention", it is unclear which claims are intended to encompass Applicant's "entirety of the subject invention". Firstly, the claims in this application encompass five different inventions (Groups I-V) drawn to five different subject matters, as stated in the last Office action. The subject matter of each invention will be examined upon its merits. Secondly, since Applicants have elected the invention of Group I and SEQ ID NO:104

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(and SEQ ID NO:7 is rejoined, upon further consideration), only those claims drawn to SEQ ID NO:104 or SEQ ID NO:7, which ^{16 Seq ID NO: 104 is deleted} encompass 1-9, 14-16, 26-46, and 55-56, will receive an examination on the merits. Claims (in Group I) that recite other than SEQ ID NO:104 or SEQ ID NO:7 will not be examined. Regarding the arguments about the restriction to a single sequence, it is noted that each nucleic acid claimed is set forth by a different SEQ ID No. corresponding to structurally different proteins. Though each of the recited sequences relate to Rht polypeptide/polynucleotide, each polynucleotide or protein is patentably distinct from the others absent a showing that the structural differences between them would have been obvious. Furthermore, while the Examiner previously had the option to examine more than one sequence in an application, databases and resource allocations at the PTO have changed, and the examination of more than one sequence on the merits in one application would present a burden on the PTO resources . Therefore, the examination of all the sequences claimed in the application will pose a series burden on the PTO resources. Therefore, the restriction requirement is still deemed proper and is made FINAL.

Finally, in response to Applicants' request for a petition, it should be noted that while Applicants can petition the restriction requirement, first Office action on the merits is required in response to Applicants' election of 12/03/01.

Claims 1-46 and 48-56 are pending in this application.

Claims 1-9, 14-16, 26-46, and 55-56 are under examination.

Claims 10-13, 17-25, and 48-54 are withdrawn as being directed to non-elected

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inventions.

ERRORS

The application should be reviewed errors. Errors appear, for example, in page 25, line 8, where "stringency can" should be changed to ---stringency can---; in line 10, "ini" should be ---in---; and in line 25, where "aids" should be ---acids---.

Objection to the specification

This application is informal in the arrangement of the specification. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.

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- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

Specifically, the specification is objected to for its omission of headings (b), (e), (f), (g)

(h), and for its omission of (j) on a separate page as required by 37 CFR 1.72(b).

The specification is also objected to because of the following informalities: for example, page 52; page 47, line 18; page 20, lines 4 and 9, recite sequence without sequence identifier (SEQ ID NO:) Applicant must submit a new CRF and paper copy of the Sequence Listing, including said sequence. Applicant must also amend the specification to include the SEQ ID NO for these sequences. The specification is also objected for reciting Figures 2, 3, 4, 6, 7, 8, 9, 11, and 12 (in pages 42-45), when no figure is labeled as such.

Claims 51 and 56 are objected for failing to recite SEQ ID NO: after the sequence.

Insertion of --- (SEQ ID NO.104) ---- before the period will obviate this objection.

Sequence Listing

1. Applicant's CRF and paper sequence listing have been entered.

Information Disclosure Statement

2. Initialed and dated copies of Applicant's IDS form 1449, Paper No 5 is attached to the instant Office action.

Drawings

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3. This application has been filed with informal drawings which are acceptable for examination purposes only. Formal drawings will be required when the application is allowed.

See the attached Notice of Draftsperson

Claim Rejections - 35 USC § 112, 2nd paragraph

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-9, 14-16, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1-3, 6, 14-15, "Aestivum" should be changed to --aestivum-- , for clarification.

Claims 2-3, 6, 14-15 are indefinite in the recitation of "obtainable" which implies that the polynucleotide can also be obtained from unidentified sources. The metes and bounds of the claims are unclear. It is suggested that "obtainable" be changed to ---obtained---. Dependent claims 7-9, and 16 are included in the rejection.

In claim 8, "similarity" and "identity" are not interchangeable.

In claim 32, "a polynucleotide" should be changed to--- the polynucleotide--- for proper antecedence.

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In claims 33 and 44, “a heterologous polynucleotide or nucleic acid vector” lack antecedence. ---comprising the isolated polynucleotide--- should be inserted after “vector”.

In claims 34-38, “A” should be changed to--- The--- for proper antecedence. In claim 36, “ a heterologous said polynucleotide” should be changed to ---the heterologous polynucleotide---, for proper antecedence. “ within its chromosome-- should be changed to ---in its genome--, for clarification. In claim 38, it is unclear what is encompassed by a “derivative of a plant”.

In claim 39, “a cell” lacks antecedence. “a cell” should be changed to ---the host cell----.

In claims 40-41, “A” should be changed to --The---, for proper antecedence. In claim 41, --further --- should be inserted before “includes”, for clarification.

In claim 42, “a” should be changed to --the---, for proper antecedence.

In claim 45, ---further --- should be inserted before “including”.

Claim 46 is indefinite for depending upon itself. A claim can only depend on a previous claim. Also, the metes and bounds of “a

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characteristics of a plant” are unclear. What characteristics are intended to include?

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 6-9, 14-16, 30-31, 55-56, and dependents 28-29, 32-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide encoding Rht polypeptide from wheat comprising SEQ ID NO:104 or 7 and transgenic plants or plant parts expressing said polypeptide, does not reasonably provide enablement for an isolated polynucleotides from any sources encoding a polypeptide comprising SEQ ID NO:104, or polynucleotides encoding a polypeptide having 80% sequence similarity with a polypeptide comprising SEQ ID NO:104 or with a polypeptide encoded by a polynucleotide comprising SEQ ID NO:105, or polypeptide with at least 10 or 16 residues similarity or identity with SEQ ID NO:104 and still retaining Rht polypeptide activity, or a polynucleotide which is complementary to at least a “50 contiguous” basis of a coding sequence, or its complementary, encoding a polypeptide comprising SEQ ID NO:104, for antisense or suppression effect. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims.

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Applicant broadly claims an isolated polynucleotide from any source, including those from slender barley mutant, encoding a polypeptide comprising SEQ ID NO:104, or a polynucleotide encoding a polypeptide having 80% sequence similarity with the Rht polypeptide comprising SEQ ID NO:104 or with a polypeptide encoded by a polynucleotide comprising SEQ ID NO:105, as well as a polypeptide with at least 10 or 16 residues similarity or identity with the amino acids in SEQ ID NO:104, or a polynucleotide which is complementary to at least a "50 contiguous" basis of a polynucleotide or its complementary encoding a polypeptide comprising SEQ ID NO:104, and still retaining Rht activity. In contrast, the specification teaches isolated polynucleotide sequences encoding Rht polypeptide from wheat comprising SEQ ID NO:104 or 7. The specification also discloses that SEQ ID NO:104 as a conservative region consisting of 17 contiguous amino acid sequence and which is disclosed as the domain responsible for Rht activity in wheat (Fig. 3a). The specification does not disclose or provide any guidance for the obtention and use of all the polynucleotides of claims 1, 6-9, 14-16, and 55-56. The specification does not provide guidance for any modifications to the disclosed sequences that resulted a polypeptide having 80% sequence similarity to a polypeptide comprising SEQ ID NO:104, or that resulted a polypeptide with 10 or 16 residues of SEQ ID NO:104 and that still retains the dwarfing activity. *In re Wands*, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the

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invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims. A polypeptide having 80% sequence similarity to a polypeptide including SEQ ID NO:104 encompass those obtainable by modifications including additions, deletions, and substitution of one or more amino acids in SEQ ID NO:104 or in a polypeptide comprising SEQ ID NO:104. The specification does not disclose which one or more of the 17 amino acids could be deleted so as the Rht polypeptide activity is retained. It is unpredictable as to whether any amino acid substitutions, additions, or deletions in any of the disclosed or non-disclosed sequences will retain the polypeptide activity. The prior art as exemplified by Lazar et al. (Molecular and Cellular Biology, March 1988, Vol. 8, No. 3, pp. 1247-1252 (U)) and Broun et al. (Science, 13 November 1998, Vol. 282, pp. 131-133 (W)), teach unpredictability in protein function when one or more amino acids in that protein is modified. Lazar et al teaches a mutation of aspartic acid 47 and leucine 48 of a transforming growth factor alpha results in different biological activities (Title). Broun et al teaches as few as four amino acid substitutions can change an oleate 12-desaturase activity (Abstract). For claims 30-31, the specification is not enabling for a polynucleotide sequence which is complementary to a sequence of at least a "50 contiguous" bases of the coding sequence of a polynucleotide or its complementary encoding a polypeptide comprising SEQ ID NO:104, said polynucleotide suitable for antisense or co-suppression of the coding sequence. It is unpredictable whether any 50 contiguous bases of the coding sequence of the disclosed sequences or a sequence complementary thereof would be suitable for use in antisense or cosuppression regulation of the expression of

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said coding sequence. The prior art teaches unpredictability in the inhibition of expression of specific coding sequence via antisense RNA in transgenic plants, due to the variation in the degree of antisense inhibition which resulted in different transgenic clones (see, e.g., BIRD et al, pages 220-221) and due to the mechanism of inhibition of gene expression by means of antisense mRNA which is not universally effective and is poorly understood (see, e.g., Sandler et al , page 301, Abstract; page 302, column 1, top two paragraphs). The antisense expression of tomato polygalacturonase gene taught by Smith et al (see, e.g., page 725, paragraph bridging columns 1 and 2) does not produce the predicted change in fruit ripening (senescence). Chory et al, who teach unpredictability in the expression of leaf senescence- genes (mutants and wild type) in *Arabidopsis thaliana* (see, e.g., page 339, Abstract; page 345, 2nd- 4th full paragraphs). See, also Napoli et al (The Plant Cell, vol. 2, pp. 279-289, 1990) who teach unpredictability inherent in the co-suppression of genes in transgenic plants (see at least, page 279, Abstract). In addition, the specification does not enable for the methods of claims 39-41 and 44-46 that utilize non disclosed sequences, and it is unclear if the incorporation of said sequences into a plant or plant cell genome would have any influence on any plant growth characteristics. Therefore, given the lack of guidance; the unpredictability inherent in protein function as evidenced by Lazar et al and Broun et al; the state of the prior art, as discussed above, one skilled in the art would not be able to practice the claimed invention without undue experimentations.

See Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the

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inventor can define it by "its physical or chemical properties" (e.g a DNA sequence) and page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

Written Description

Claims 1-2, 6-9, 14-16, 28-46, and 55-56 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of polynucleotide sequences or parts thereof from a multitude of sources encoding Rht polypeptides or residues thereof. In contrast, the specification only provides guidance for the Rht polypeptide/polynucleotide sequences from wheat. The specification does not provide any specific chemical or physical characteristics for the polynucleotide sequences with 80% sequence similarity to the disclosed sequence or fragments or residues thereof, and a review of literature does not indicate that such characteristics would be well known by an skilled artisan. Therefore, it is unclear if Applicant in possession of the said polynucleotides/polypeptide sequences, plants or plant cell comprising them, or the methods for using them. Further, claim 1 is drawn to a polynucleotide sequence encoding any polypeptide comprising SEQ ID NO:104. SEQ ID NO:104 is a partial polypeptide encoded by a partial DNA, SEQ ID NO:105. The claims encompass complete protein sequences from various sources, including mutants and allelic variants, having common SEQ ID NO:104 which Applicant was

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clearly not possession at the time the application was filed. Thus, given the breadth of the claims which reads on proteins encoded by genes yet to be discovered in addition to numerous fusion constructs and cDNAs; and in view of level of knowledge and skill in the art, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of the genus of polynucleotides encoding a polypeptide which comprises SEQ ID NO:104, since SEQ ID NO:104 is only a partial polypeptide encoded by a partial DNA. Therefore, a person skilled in the art would not recognize from the disclosure that Applicant was in possession of the invention as broadly claimed.

See, Written Description Examination Guidelines published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices). See, also *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

Remarks

Claims 1-9, 14-16, 26-46, and 55-56 are deemed free of the prior art.

Claims 4-5 and 26-27 are allowable.

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Claim 3 would be allowable if rewritten to overcome the rejection(s) under 35

X U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina a. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00AM to 6:00PM and Wednesday-Thursday from 9:00AM to 3:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

January 30, 2002

mai

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1800

Elizabeth McElwain